

Remarks

This paper is responsive to the Office Action mailed August 24, 2005, which set a three-month shortened statutory period for response, to end November 24, 2005. This paper is timely filed within three months of the Office Action.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office rejects claims 1, 23-25, 27 and 28 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirements, and claims 1, 23-25, 27 and 28 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirements.

Applicant respectfully submits that the written description and enablement requirements are satisfied with regard to claim 1. Applicant has amended claim 1 to make it even more clear that the DESC1 mRNA recited can be derived from the cDNA listed as SEQ ID NO: 1 or SEQ ID NO: 3.

However, Applicant respectfully submits that support for **all** nucleic acids that could hybridize to DESC1 mRNA is not required. One of ordinary skill in the art could easily and without undue burden determine which nucleic acids are contemplated under the conditions set forth in claim 1. The design of nucleic acids that hybridize to a known target nucleic acid with a specific Tm is a routine matter for one skilled in the art. Since it is abundantly clear that the target nucleic acid is DESC1 and the nucleotide sequence of DESC1 is provided, one of ordinary skill in the art would have no difficulty in identifying nucleic acids that specifically hybridize to DESC1 under the conditions set forth in the claim.

Furthermore, Applicant has clearly described that the invention involves detecting the expression of the DESC1 gene as a diagnostic tool for the identification of squamous cell

carcinoma and prostate cancer. The DESC1 cDNA is clearly described in Figures 1A and 1B. Applicant also clearly demonstrates that expression of DESC1 is reduced or absent in squamous cell carcinoma and prostate cancer. Once all of these steps of the invention are known, one of ordinary skill in the art would have no difficulty in ascertaining the identity of a nucleic acid that may be used under the conditions described to determine the level of DESC1 expression.

Applicant respectfully submits that the enablement requirements and written description are clearly satisfied and the Office's rejections should be withdrawn.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 1, 23-25, 27 and 28 under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite for the recitation of the term DESC1 as the sole means of identifying the “claimed polypeptide.” Applicant assumes that the Office made an inadvertent error in stating “. . . the claimed polypeptide,” and meant to state the claim polynucleotide, as no polypeptide sequence is claimed in the pending application. (Page 4, lines 11-13 of August 24, 2005 Office Action).

Applicant is entitled to act as his own lexicographer (see MPEP 2111.01 part III). In this instance, Applicant has clearly defined DESC1 in the specification. For example, at page 1 lines 19-21, the specification states that: “The method comprises providing a sample from the subject and assaying for the presence, or absence or reduced level of expression of a novel gene, **hereinafter referred to as the “DESC1 gene”.**” (Page 1 of the application, lines 19-21, emphasis added; see also Figures 1A and 1B.) These are but one example, and the specification uses the term DESC1 consistently. The fact that different laboratories may use the same laboratory designations to define completely distinct molecules is of no consequence since Applicant has provided an explicit definition of the term DESC1. The definition given by

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Applicant will control the interpretation of the term as it is used in the claim. See *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999), which states that the meaning of words used in a claim is not to be construed in a “lexicographic vacuum, but in the context of the specification and drawings.” (see MPEP 2111.01 part III). Therefore, Applicant respectfully submits that the claims are not indefinite and the Office’s rejection should be withdrawn.

If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 03-0172.

Respectfully submitted,

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Sean Myers-Payne

Sean C. Myers-Hayne
Reg. No. 42,920
(614) 621-7754
(614) 621-0010 (fax)
smyers-payne@calfee.com